

**European Participation in U.S. Federal Science & Technology  
Research Funding Programmes:  
Survey of Researchers and Institutions  
on National Institutes of Health Grant Funding**

*Main Report*



February 2011

## About the Link2US Project

The Link2US project facilitates easy access to relevant information on U.S. cooperation programmes through electronic communities such as a website, e-newsletter, and virtual helpdesk and designated activities such as training workshops.

Link2US is:

- Mapping opportunities of U.S. federal collaborative funding schemes and rules for participation through research and analyses.
- Raising awareness among the European scientific community by disseminating information about programmes and funding opportunities through a multi-faceted network.
- Identifying and analyzing potential obstacles to cooperation through these programmes and funding schemes so that they may be avoided and/or that solutions may be found.

Link2US is coordinated by the American Association for the Advancement of Science (AAAS) and implemented together with the Austrian Research Promotion Agency (FFG), Hungarian Science & Technology Foundation (TETALAP), and Italy's Agency for the Promotion of European Research (APRE).

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For more information:

[www.EuUsScienceTechnology.eu/Link2US/](http://www.EuUsScienceTechnology.eu/Link2US/)



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## Disclaimer

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## Executive Summary

European Union (EU)-based researcher and institution participation in United States (U.S.) federal science and technology (S&T) research funding programmes is significantly impacted by a diverse set of rules and regulations. Participation can and does take place in various forms, from direct funding to subcontracting to cooperative agreements. The U.S. National Institutes of Health (NIH) has the largest programmes in which there is direct funding of EU-based researchers and institutions. The *European Participation in U.S. Federal Science & Technology Research Funding Programmes: Survey of Researchers and Institutions on NIH Grant Funding* surveyed EU-based researchers and institutions, through their grants administrators, who have received direct NIH awards during U.S. fiscal year 2003-2010 to identify key issues that they face when applying to and participating in NIH funding programmes.

The survey asked researchers and grants administrators (GA's) about their experiences with NIH, on issues ranging from awareness of opportunities to legal, policy, and administrative aspects of programme participation, and recommendations for lessons and improvements to support further U.S. and European cooperation. Responses were received from 78 researchers (out of 308 contacted) and 18 GA's (out of 88 contacted) and were dominated by those from the United Kingdom with significant numbers also from Sweden, Germany, France, and Italy.

The survey found:

**NIH programmes were researcher-friendly but policy differences between NIH and European institutions make grant administration challenging.**

Researchers overall had positive experiences with NIH and its programmes. Researchers described most of the issues raised in the survey as less challenging compared with other, non-NIH programmes, including areas of cultural differences in grant management; broad administrative and contractual issues, including auditing, budgeting, and intellectual property (IP); differences in U.S. and European policies; additional review criteria for non-U.S.-based applicants; and lack of complementary funding. A plurality of researchers indicated that improved administrative support from their own organizations, clarity about eligibility and other requirements for non-U.S.-based institutions, and facilities and administrative (F&A) cost recovery were more challenging issues than with other programmes.

European GA's experienced overall more challenges than researchers. Besides the challenges of F&A cost recovery and communication and information awareness, especially how NIH policies and EU-applicable opportunities and requirements are presented (e.g., difficulties in understanding U.S. legal language), a plurality or majority of GA's also indicated the following issues as more challenging compared with other, non-NIH, programmes: differences between U.S. and European policies; lack of administrative support from NIH; audit requirements, IP, and other contractual issues.

**NIH's funding system was praised as transparent and highly respected with helpful NIH programme staff.**

Both researchers and GA's highlighted NIH's peer review system, particularly its transparent review process and feedback mechanisms, as one of the most positive aspects of its programmes and an example for other funding entities. Moreover, both groups remarked on the relative bureaucratic ease of NIH programmes and on the helpfulness of NIH programme staff.

**Suggestions focused on improving already open and efficient NIH programmes.**

To further improve research collaboration between the United States and Europe through NIH programmes, researchers and GA's suggested improving clarity of eligibility criteria and opportunities for EU-based researchers, increasing support for addressing NIH and European differences in administrative requirements and policies, developing specific funding for U.S.-European collaboration, and allowing full F&A cost recovery. Besides some very practical ways to enhance the existing programmes like improving communication and information awareness, the survey results suggest two areas that would be useful for further elaboration: exploration of policy requirements (e.g., ethical, health, safety, etc.) that could be better harmonized between the U.S. and Europe; and the structure of potential new, specific U.S.-European instruments.

## Background

European Union (EU)-based researchers and institutions can and do participate in United States (U.S.) funding programmes (e.g., in cooperative agreements and receiving subcontracts and direct funding). The nature of their participation is determined by a diverse set of policies and regulations. This diversity is a result of the decentralized nature of the U.S. research funding system as a whole, as funding authority is spread across over a dozen or more federal entities (i.e., from executive agencies to cabinet departments and their sub-units), each with its own policies and regulations. Out of 11 civilian U.S. science and technology (S&T) research funding entities, three have programmes that can directly fund EU-based researchers through their institutions. These entities are the U.S. Department of Energy (DOE), the U.S. Department of Homeland Security (DHS), and the U.S. National Institutes of Health (NIH).<sup>1</sup> In addition to these three, many of the other U.S. funding entities do not usually restrict, and indeed oftentimes encourage, cooperation between researchers in the U.S. and foreign institutions as long as the foreign institutions are funded by other means.

## Objective

The main objective of this study, *European Participation in U.S. Federal Science & Technology Research Funding Programmes: Survey of Researchers and Institutions on NIH Grant Funding*, is to identify key issues that EU-based researchers and institutions face when applying to and participating in NIH funding programmes that directly provide research grants to them. NIH is the largest direct funder of EU-based researchers and institutions with publicly accessible information about grantees. A survey was conducted of EU-based researchers and institutions who have directly received U.S. grants. The analysis of the survey contained in this report seeks to inform EU and U.S. stakeholders, including the European Commission and U.S. funding entities, on the most salient issues of programme participation from the European perspective and feed into efforts to further understand and address how European and U.S. researchers and institutions can better cooperate, with reciprocal direct funding as one mechanism for cooperation. A survey of EU-based researchers participating in DOE programmes will be presented separately; and a Link2US workshop will be held in 2011 as a follow-up activity to further elaborate these key issues.

## Methodology

NIH grantees and their institutions were the focus of the survey. EU-based researchers and their institutions who have received NIH grants and other awards were surveyed about their experiences in various aspects of seeking, applying for, and receiving these grants. The survey was conducted using two separate questionnaires, administered through a commercial web-based system – SurveyMonkey™ ([www.surveymonkey.com](http://www.surveymonkey.com)). The survey focused on awards received in fiscal year (FY) 2003-2010.<sup>2</sup> Each individual surveyed received an introductory letter via email about the Link2US project and the goal of the questionnaire

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<sup>1</sup> NIH is part of the U.S. Department of Health and Human Services. More information on U.S. funding programmes open to EU-based researchers and institutions can be found in this previous Link2US report: <http://www.euussciencetechnology.eu/link2us/funding-opportunities.html>

<sup>2</sup> The U.S. federal fiscal year runs from 1 October of the previous year to 30 September of the given year.

along with a link to fill out the questionnaire. Individuals were able to complete the questionnaire in multiple sessions.

One questionnaire was sent to the principal investigators (PI's) who directly received NIH awards through EU-based institutions. PI names and affiliations were compiled from NIH award statistics publicly available on the NIH Research Portfolio Online Reporting Tool's (RePORT) official website.<sup>3</sup> Contact information was found through internet searches, primarily from the websites of the researchers' institutions. The PI questionnaire was administered from 14-28 September 2010. See appendix 1A and 1B for the introductory letter and questionnaire.

The other questionnaire was directed at grants administrators (GA's) at the institutions where researchers have received NIH awards. Institution websites were used to identify a point of contact, if available, for the questionnaire. While many institutions that did have NIH grantees did not have an identifiable GA's, those that had multiple NIH grantees or awards typically had a GA. Two rounds of the GA questionnaire were administered, the first from 14-28 September 2010 and a second round on 27 September-11 October 2010, in order to reach as many of the GA's as possible from the multi-award institutions. See appendix 2A and 2B for the GA introductory letter and questionnaire.

The questionnaires contained three broad types of questions: the first related to basic demographic information of the respondent and their background in relation to the funding entity; the second type addressed various aspects of the respondent's experience with the funding entity and its programmes (e.g., awareness, legal, policy, and administrative issues); and the third type addressed recommendations for lessons and improvements. While broadly similar, the questionnaires were customized to each of the two surveyed groups as described below. Beyond the common questions in all questionnaires, researchers were asked specifically about how NIH funding contributed to their overall research programmes. And GA's were additionally queried about how their institution approached challenges to participation in NIH programmes.

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<sup>3</sup> Data was collected on 31 July 2010 from <http://report.nih.gov/index.aspx>.

## Results

NIH is the primary U.S. federal entity for conducting and supporting biomedical research. NIH programmes fund the largest number of EU-based researchers and institutions of all U.S. civilian programmes. Moreover in 2008, the then Director of NIH Elias Zerhouni and European Commissioner for Research Janez Potočnik agreed to the mutual openness of NIH funding programmes and the Framework Programme for biomedical and health research.<sup>4</sup>

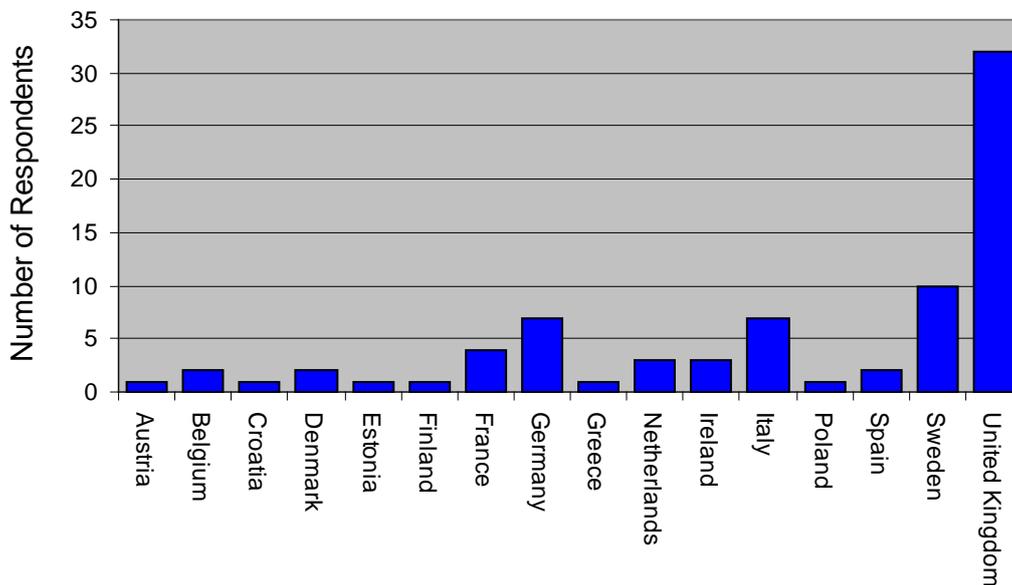
## Researcher Responses

NIH awarded 1,097 new grants to 326 individual EU-based researchers in FY2003-2010. Out of the 308 researchers whose contact information was publicly available, 78, or 25%, responded to the questionnaire.

## Demographics

Several key demographic information were captured of the responding researchers, including location of their institution, type of their institution, number of new NIH grants awarded, and education in and collaboration with U.S. institutions before first NIH grant was awarded.

Figure 1.1: Member State of Current Institution

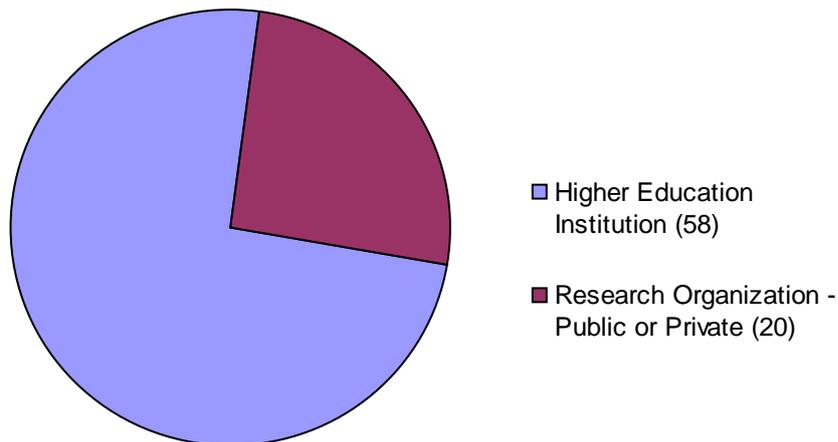


The responding researchers were based in 16 EU member states (MS), as shown in Figure 1.1. The United Kingdom had the highest number of researchers responding, with 32 individuals. Sweden followed with 10, Germany and Italy each with 7, France with 4, and Ireland and the Netherlands each with 3. The remaining 9 countries only had one or two

<sup>4</sup> E.A. Zerhouni, J. Potocnik, Science 322; 1048 (2008).

respondents. The representation of responses received corresponds roughly to what would be expected from the relative representation of MS receiving NIH awards. Sweden is an exception, as researchers from Germany, Italy, and France typically receive more grants than Sweden from NIH each year.<sup>5</sup> See appendix 1C for all data.

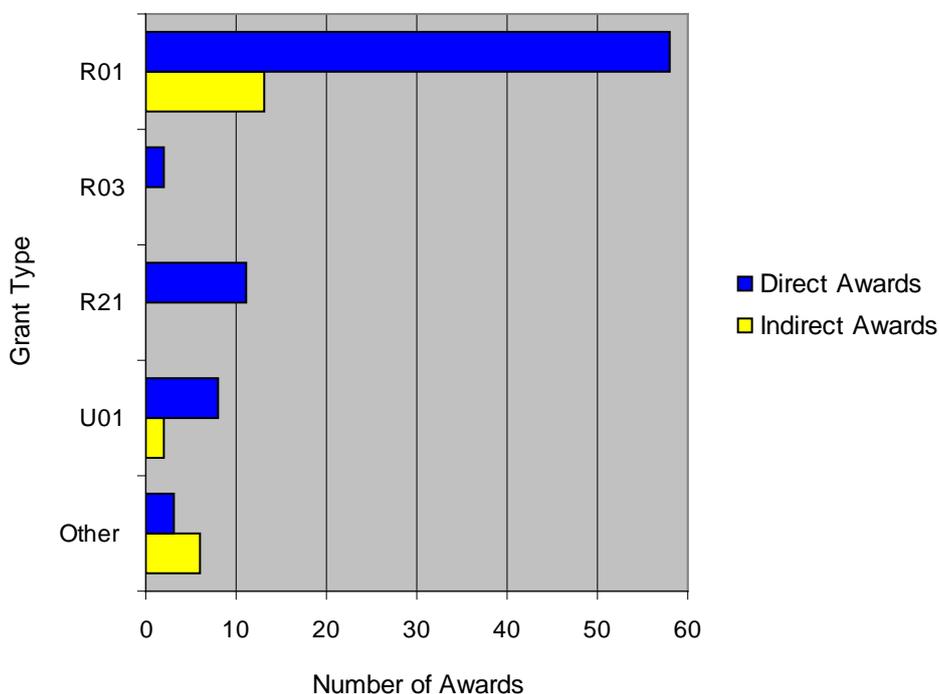
Figure 1.2: Breakdown of Responding Researchers' Organization Type (Number of Responses)



The majority of responses, 74%, came from higher education institutions, as shown in Figure 1.2. The other respondents were based in public or private research organizations. No respondent came from industry; only four of the hundreds of researchers contacted (and who received NIH awards) were in industry. See appendix 1D for data.

<sup>5</sup> For more information about the participation rates of EU-based researchers in U.S. programmes, please refer to the report, *Participation Statistics of EU-based Researchers in U.S. National Programmes*, available at: [http://www.euussciencetechnology.eu/uploads/news/LU\\_T1.5\\_Statistics%20Draft\\_Final\\_WebsiteVersion.pdf](http://www.euussciencetechnology.eu/uploads/news/LU_T1.5_Statistics%20Draft_Final_WebsiteVersion.pdf)

Figure 1.3: Number of New NIH Grants Awarded to Respondents Between FY2003-2010



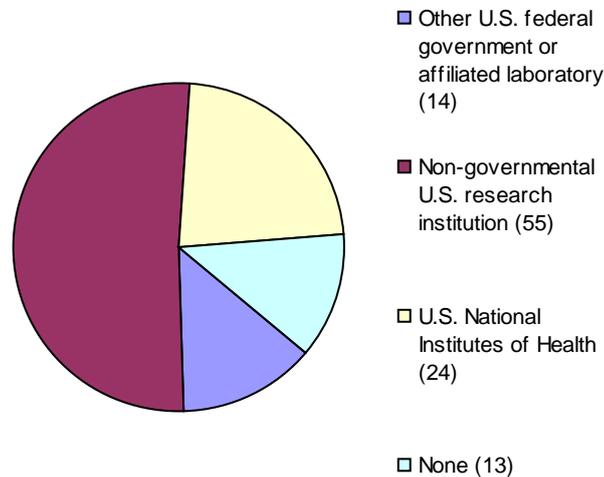
Eighty-two (82) direct awards were received by responding EU-based researchers between FY2003-2010. The majority of responding researchers were funded through the NIH Research Grant Programme (R01), with 58, as shown in Figure 1.3. The other awards received were NIH Exploratory/Developmental Research Grant Award (R21), with 11, Research Project Cooperative Agreement (U01), with 8, and NIH Small Grant Programme (R03), with 2. Awards reported as other were PPG (NIH Research Program Projects and Centres series) with 2, and R19 (Research Grant series), with 1.<sup>6</sup> The predominance of R01 grantees in the respondents is consistent with the predominance of R01's in awards to EU-based researchers.

While the survey targeted those researchers who received direct awards, some of the responding researchers also received indirect awards, such as foreign components of U.S. domestic awards or subcontracts. For the 21 indirect awards received by respondents, the R01 again was reported as the primary mechanism with 13. U01's were reported on a smaller basis, with only 2, while no R21 or R03 awards were reported received. The 6 other awards reported by researchers were: High Impact Research and Research Infrastructure Programs, RC2 (1), Research Program Projects, P01 (2), NIH Support for Conferences and Scientific Meetings, R13 (1), Biotechnology Resource Cooperative Agreements, U41 (1), Specialized Centre-Cooperative Agreements, U54 (2), and a Bioengineering partnership, BRP (1). See appendix 1E for data.

<sup>6</sup> NIH award codes periodically are updated, resulting in some grant codes no longer in use.

A majority of the responding researchers, 72%, had previously studied or conducted prior research in the U.S. before receiving their first NIH award. See appendix 1F for data.

Figure 1.4: Type of U.S.-Based Institution Researcher Previously Collaborated with Before First NIH Grant was Awarded (Number of Responses)



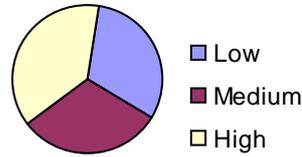
In addition, prior collaboration with U.S. federal or non-governmental agencies is also quite common before applying to NIH grants. Eighty-eight percent (88%) of respondents had previously collaborated with U.S. institutions prior to receiving their first NIH grant. The majority, 52%, indicated collaborations with non-governmental U.S. research institutions, as shown in Figure 1.4. Twenty-three percent (23%) of researchers had previously collaborated with NIH, and 13% previously collaborated with other U.S. federal government or affiliated laboratories. Researchers from both higher education institutes and research organizations reported a similar prevalence of prior collaborations. See appendix 1G for a further breakdown of data.

### General Challenges

The questionnaire sought to capture the relative importance of various general issues that EU-based researchers may face when participating in NIH funding programmes. The issues, as shown in Figure 2.1, were communication and information awareness of programmes; lack of administrative support from own organization; cultural differences in management of grants; lack of administrative support from U.S. funding bodies; contractual issues and intellectual property; differences and/or lack of recognition between U.S. and EU policy requirements on issues such as animal safety, protection of human subjects, research integrity, etc.; and lack of complimentary funding. Researchers were asked to rate, from 0-5 by increasing degree of challenge, how each issue was a “high” (if rated 5-4), a “medium” (if rated 3), or a “low” (if rated 2-0) challenge as compared with other, non-NIH, programmes.

Figure 2.1: General Challenges to Participation in NIH Funding Programmes (Shown as High, Medium, or Low)

Figure 2.1.1

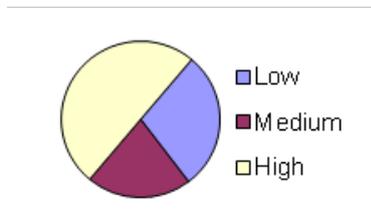


A: Communication and Information Awareness of Programmes



B: Lack of Administrative Support from own Organization

Figure 2.1.2

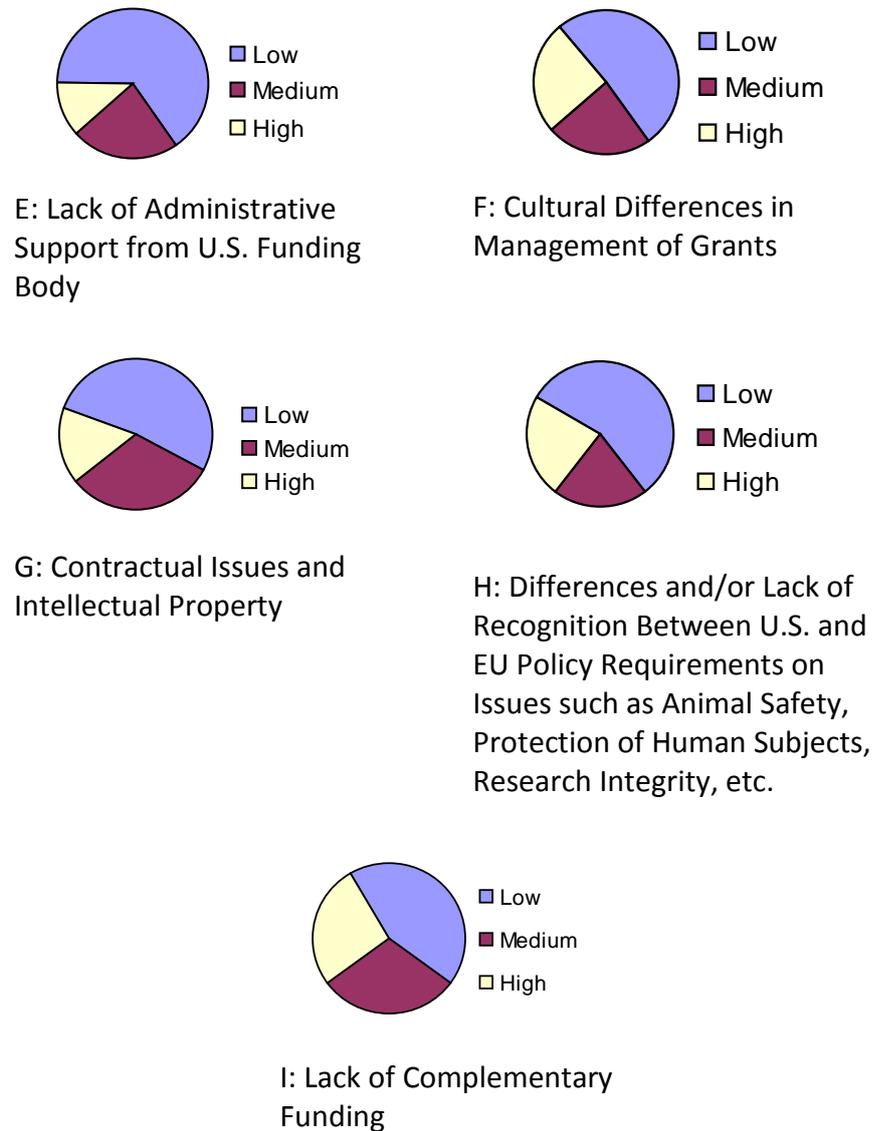


C: Lack of Administrative Support from own Organization (only Researcher Responses from Institutions where no GA's were Identified)



D: Lack of Administrative Support from own Organization (only Researcher Responses from Institutions where their GA's also Responded)

Figure 2.1.3



Of the seven issues, two were identified as more challenging than the others, with a plurality of researchers responding in the “high” category -- communication and information awareness of programmes and lack of administrative support from own organization. Thirty-eight per cent of respondents described communication and information awareness of NIH programmes, shown in Figure 2.1.1A, as a “high” relative challenge. Figure 2.1.1B depicts the issue of lack of administrative support from own organization, where 47% of researchers identified it as a “high” challenge. Looking more closely at responses to this particular issue, a majority of those researchers responding from institutions where GA’s could not be identified indicated that this was a “high” challenge, shown in Figure 2.1.2C, as would be expected. Whereas a majority of researchers responding from institutions where there were GA’s who also responded to the survey indicated that it was a low “challenge” issue, as shown in Figure 2.1.2D.

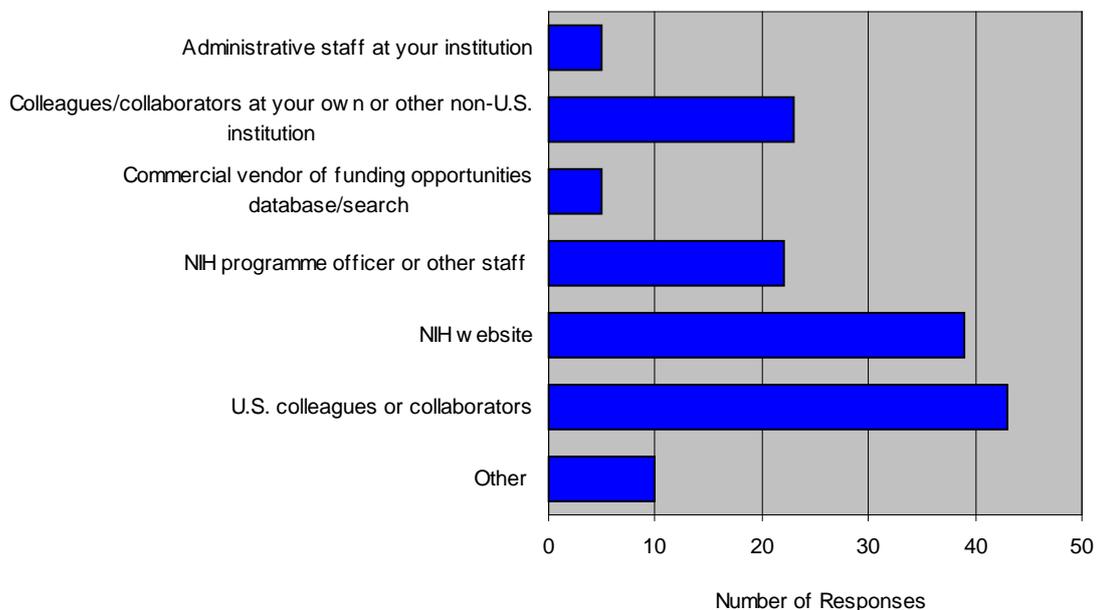
Five issues were described by a majority of respondents, or a plurality for the last issue, as “low” relative challenges -- lack of administrative support from U.S. funding body (65%), cultural differences in management of grants (51%), contractual issues and intellectual property (53%), differences and/or lack of recognition between U.S. and EU policy requirements (56%), and lack of complementary funding (44%) -- as shown in Figure 2.1.3.

Researchers were also asked to identify other areas of concern that may have been captured by the seven explicitly provided issues. The majority of the 14 open-ended responses indicated one of two areas: problems with overhead costs (i.e., F&A) and the “uniqueness” factor needed to receive NIH funding as an internationally-based applicant. Both issues were explored in other parts of the questionnaire and are further discussed in subsequent sections of this report. See appendix 1H for detailed ratings on the general issues and all comments.

### Information and Awareness Challenges

EU-based researchers were also asked more specifically about information and awareness issues pertaining to NIH funding programmes. When it comes to hearing about new NIH funding opportunities, 76% of EU-based researchers responded that new opportunities are easy to find out about. Several researchers who replied that opportunities are difficult to find stated that NIH newsletters and website have too much information available, making it difficult to identify specific opportunities relevant to them. See appendix 1I for the detailed comments.

Figure 3.2: How Researchers Hear About New NIH Opportunities



Researchers were asked to select from a list of resources from which they hear about new NIH opportunities (more than one option could be selected). The most common source, which 43 researchers selected, is their U.S. colleagues or collaborators. The NIH, either through its website (39) or NIH staff (22), is also a common source. Closer to home, 23

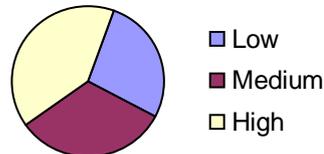
researchers reported that they hear about new opportunities from colleagues at their own or other European institutions. Few researchers indicated that they hear about new opportunities from administrative staff at their own institutions or from commercial vendors. “Other” sources that researchers described included articles, e-alerts, newsletters, scientific meetings, and researchers who were previously based in the U.S. See appendix 1J for a further breakdown of all data. When asked about any other issues related to awareness of opportunities that the questionnaire did not cover, the responses were limited and mixed. See appendix 1K for the detailed responses of “other” issues.

### Legal, Policy, and Administrative Challenges

Legal, policy, and administrative issues related to EU-based researcher participation in NIH funding programmes were probed in further detail. As with the general issues question, researchers were asked to rate, from 0-5 by increasing degree of challenge, five issues on how each was a “high” (if rated 5-4), a “medium” (if rated 3), or a “low” (if rated 2-0) challenge as compared with other, non-NIH, programmes. Facilities and administrative (F&A) cost recovery limits, audit requirements, budgeting requirements, intellectual property, and other contractual (grant) requirements are the five focal issues described in Figure 4.1.

Figure 4.1: Legal, Policy, & Administrative Challenges to Participation in NIH Funding Programmes

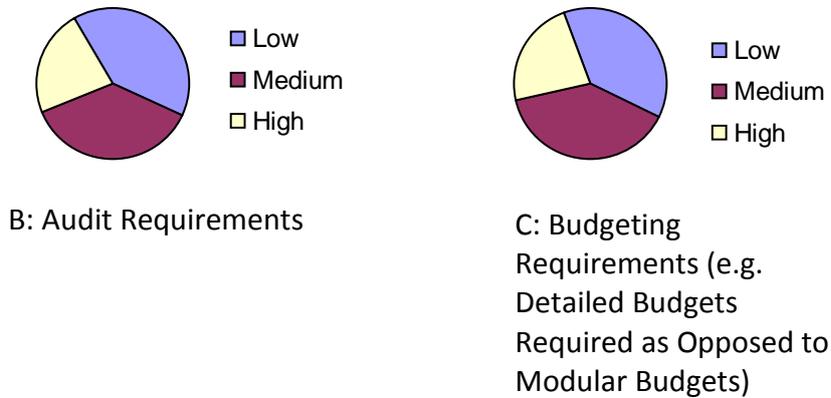
Figure 4.1.1



A: Facilities & Administrative (F&A) Cost Recovery Limits

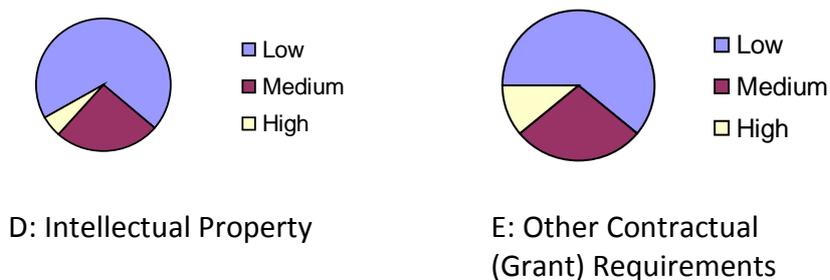
The plurality of researchers, 40%, indicated that F&A cost recovery limits was a “high” challenge, as shown in Figure 4.1.1A.

Figure 4.1.2



Two issues, audit requirements and budgeting requirements, were described by researchers as fairly evenly split between “low” and “medium” challenges, as shown in Figure 4.1.2. Audit requirements, as show in Figure 4.1.2B, was identified by 40% of the respondents as a “low” relative challenge; 36% described the issue as a “medium” challenge. Budgeting requirements (e.g. detailed budgets versus modular budgets) was similarly described by researchers. Figure 4.1.2C shows that 38% of researchers identified this issue as a “medium” relative challenge while 37% said it was a “low” challenge.

Figure 4.1.3



Two issues, intellectual property and other contractual (grant) requirements, were described by the majority of researchers as “low” relative challenges, as shown in Figure 4.1.3. Intellectual property, shown in Figure 4.1.3D, was described by 68% of researchers as “low”. Similarly, 56% of researchers described other contractual (grant) requirements, shown in Figure 4.1.3E, as a “low” relative challenge. See appendix 1L for all data.

In addition to asking researchers to rate various issues, researchers were asked specifically about their experience with satisfying the specific criteria in the NIH Grants Policy Statement affecting non-U.S. PI's. According to the Statement, proposals originating from outside the United States (but not U.S. domestic applications with foreign components) are subject to these additional review criteria:<sup>7</sup> 1) whether the project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources; and, 2) whether the proposed project has specific relevance to the mission and objectives of the NIH Institute/Centre (IC) and has the potential for significantly advancing the health sciences in the United States and the health of the people of the United States.

With 77 researchers responding, 65% responded that they had not experienced challenges due to these criteria. The 35% responding they had experienced challenges were asked to explain their response, which can be found in appendix 1M. The responses varied and there was no single overriding explanation. Several noted that having an U.S. collaborator eased the justification to satisfy the policy criteria and others expressed a perceived bias against non-U.S.-based applicants.

Finally, researchers were asked to identify other legal, policy, and administrative concerns not already specified. There was no general consensus on other issues of concern. Local customs, NIH administration assistance, and assistance from researchers' home institution were some of the other issues listed. See appendix 1N for detailed breakdown of researcher comments.

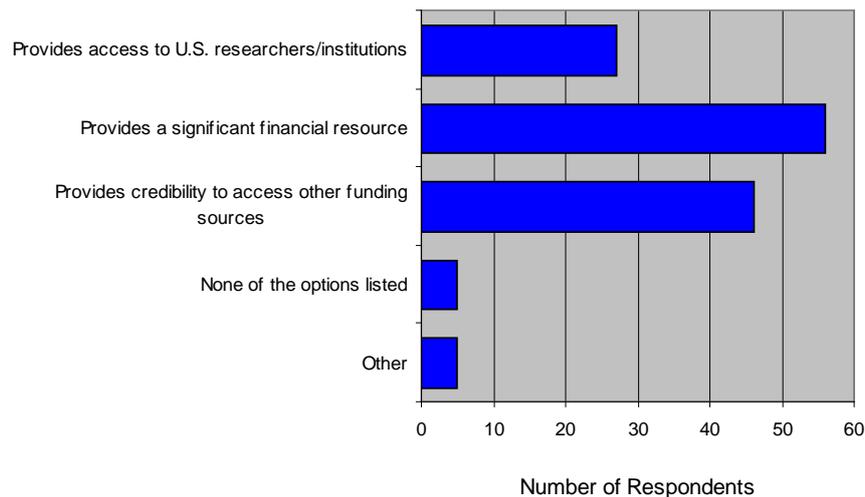
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<sup>7</sup> From NIH Policy Notice #NOT-OD-09-010 (released October 8, 2008) "Updates and Reminders on NIH Policy Pertaining to Grants to Foreign Institutions, International Organizations and Domestic Grants with Foreign Components;" the latest version of the NIH Grants Policy Statement, issued October 1, 2010, can be found at <http://grants.nih.gov/grants/policy/>, see specifically Part II, Subpart B, Chapter 16 for grants to foreign institutions.

## Contribution of NIH Funding

Researchers were also asked about how NIH funding contributed in various ways to their overall research programmes.

Figure 5.1: Contribution of NIH Funding to Overall Research Programme (Number of Responses)

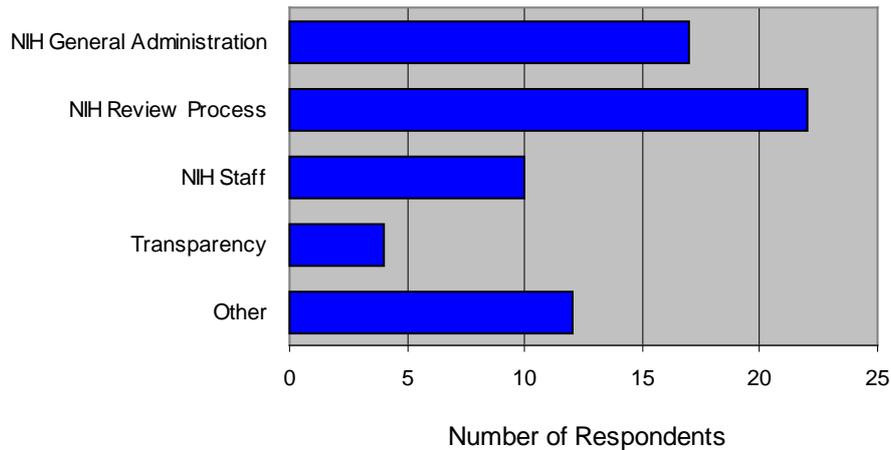


Researchers were asked to select all the statements that applied, as shown in Figure 5.1. The plurality of researchers, 72%, reported that NIH provided a significant financial source. “Significant” was defined in the questionnaire as greater than 25% of a researcher’s total research funding. Fifty-nine per cent of the researchers said that NIH funding provided credibility to access other funding sources. Please see appendix 10 for all data.

## Positive NIH Experiences/Aspects/Issues

In addition to asking researchers to identify and rate how various issues were challenges, researchers were asked to comment on positive experiences, aspects, and issues when applying for and/or receiving NIH awards that could be lessons for other, U.S. or European, funding entities. Over 70% of the respondents commented on this open-ended, optional question. While the 57 comments received greatly varied, they could be grouped into five themes (with six comments included in two themes and one included in three), as summarized in Figure 6.1.

Figure 6.1: Positive Experiences, Aspects, and Issues between Researchers and NIH



The largest number of the comments, 39%, focused on the NIH review process, especially its feedback system, as a strength of the NIH programmes. Specifically, the ability to view reviewers' comments and resubmit enhanced proposals is very important to the respondents, and one of the most positive aspects of dealing with NIH. One researcher stated that "the peer review mechanism of NIH grants is a model for any funding agency." Another stated that "I believe the NIH grant review system is still the best existing because it gives the possibility to PI's to answer in a new application to criticisms received during the review process. I have never seen this in the review process of European agencies."

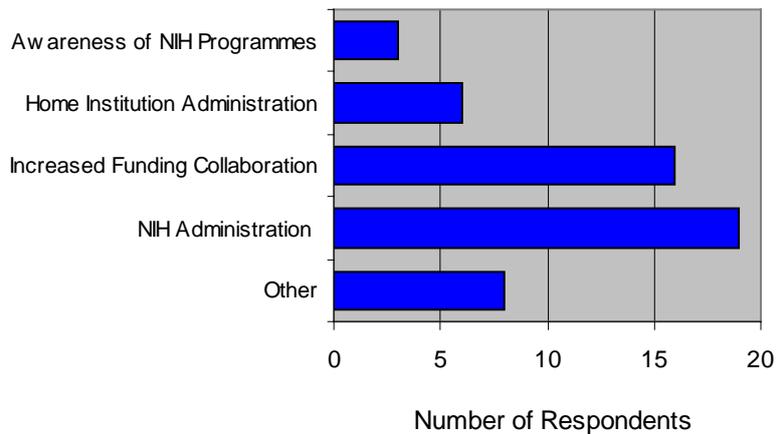
Thirty per cent of the comments relayed positive experiences with various aspects of NIH general administration. One researcher stated that "applying for an NIH grant from outside the U.S. would be completely impossible without the extensive NIH guides that are most informative and exemplary for any application system" while another stated "I find the NIH system excellent, far less burdensome than EU funding..."

The third most commented theme, with 18% of the comments, related to NIH staff. Respondents praised individual programme officers for opportunities to closely collaborate with them and staff professionalism. See appendix 1P for a detailed breakdown of researcher comments.

### Researcher Recommendations

Finally, researchers were asked to make recommendations based on their experiences that could ease or improve research collaboration through NIH funding programmes. While the 49 comments received greatly varied, Figure 7.1 summarizes the main themes found. Due to the open-ended question format, three comments were included in two themes.

Figure 7.1: Researcher Recommendations to Ease or Improve NIH Research



Recommendations to enhance various aspects of NIH administration received the largest set, 39%, of comments. Aspects included improved communication from NIH administration, increased awareness of differences in administrative and financial management by the EU and NIH, and greater clarity and fairness in reviewing non-U.S.-based research proposals.

While most of the main themes addressed in the recommendations relate to those issues addressed explicitly in the questionnaire, the issue of increased funding collaboration was not addressed. Thirty-three per cent of the recommendations focused on this theme, including for example, establishing structures to jointly fund EU-U.S. research teams.

Other comments surrounded increasing administrative knowledge at the researcher’s home institution and increasing awareness for NIH programmes. See appendix 1Q for detailed researcher comments.

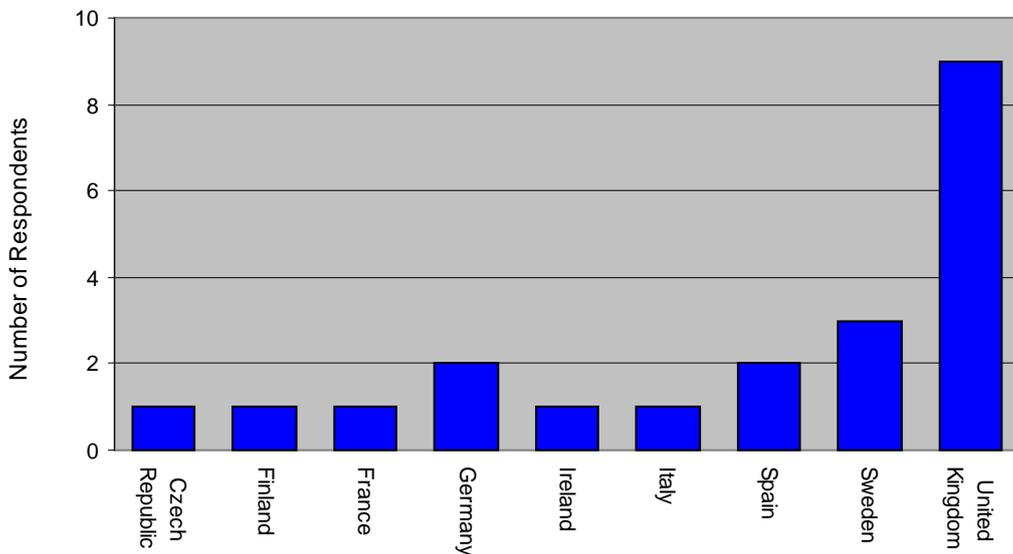
## Grants Administrator Responses

For FY 2003-2010, 191 EU-based institutions received new NIH awards. Out of these institutions, 88 were surveyed that had identifiable contact points for central grant administration. A total of 18, or 20%, of grants administrators (GA's) responded to the questionnaire (note that not all responded to all questions).

### Demographics

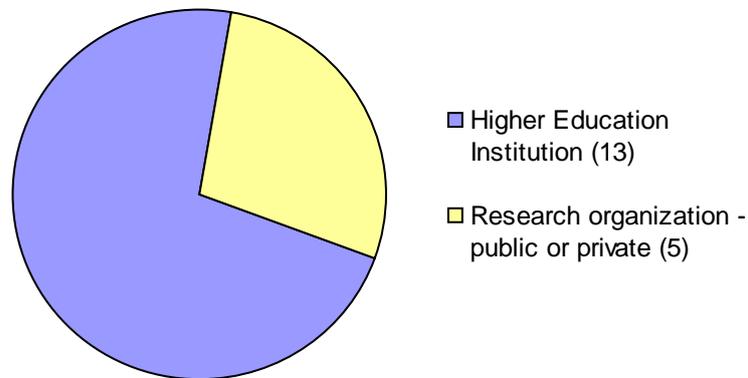
Demographic information captured from the responding GA's included location of their institution, the type of their institution, and number of direct versus indirect awards received from NIH.

Figure 8.1: Member State of Current Institution



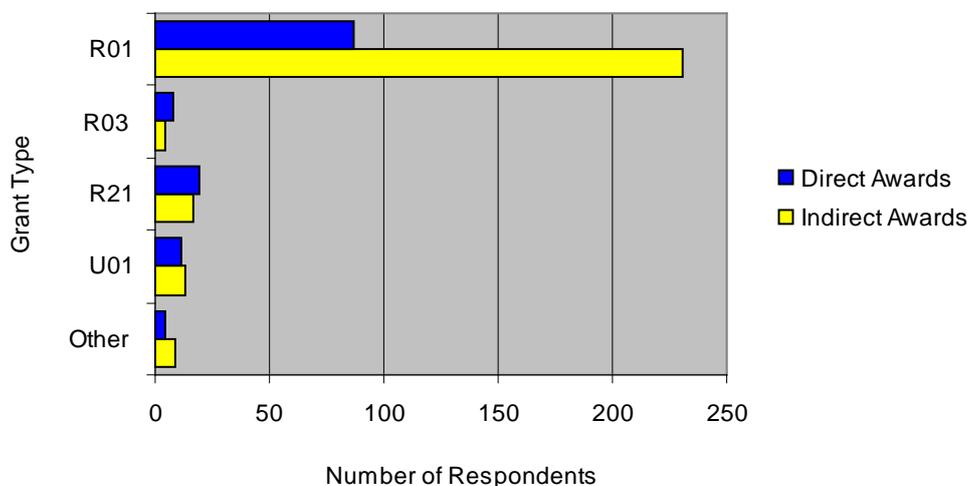
The responding GA's were based in nine MS, as shown in Figure 8.1. Note that one GA responded based on their experience at institutions from four separate MS. The United Kingdom had the highest number of GA's responding, with 50% of the respondents, followed by Sweden, Germany, and Spain. See appendix 2C for a further breakdown of data.

Figure 8.2: Breakdown of Responding GA's Organization Type (Number of Responses)



The majority of the respondents, 72%, came from higher education institutions, as shown in Figure 8.2. The others identified themselves as research organizations, either public or private. See appendix 2D for the data.

Figure 8.3: Number of New NIH Grants Awarded to Institutions Between FY2003-2010



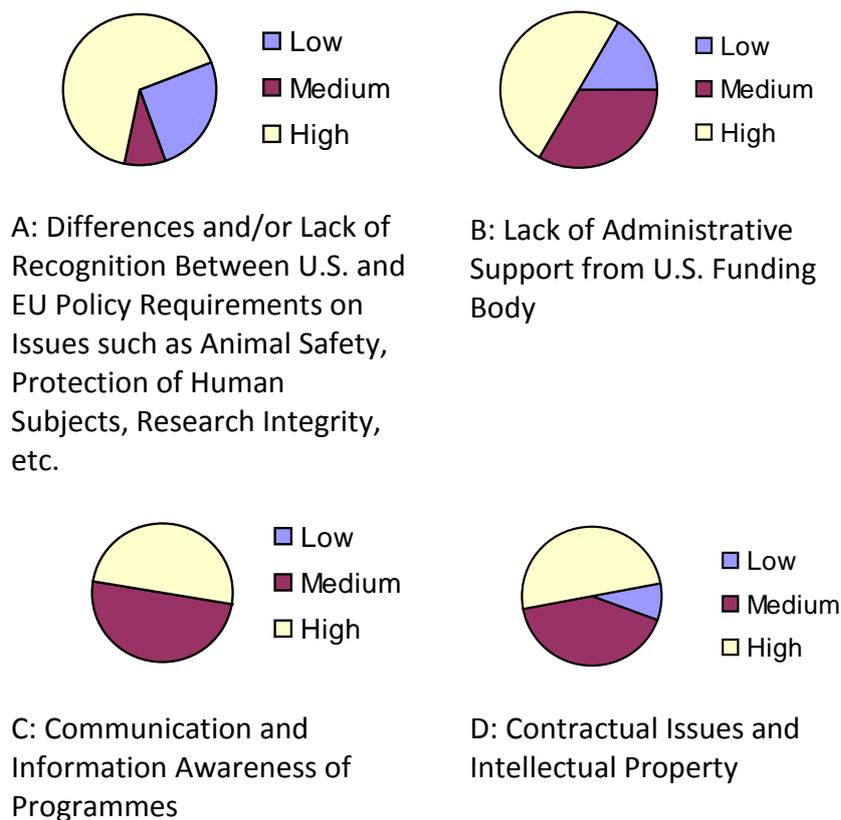
The majority of responding GA's primarily handled the NIH Research Grant Programme (R01) awards, with 87 direct and 231 indirect awards reported, as shown in Figure 8.3 (note for this question, 13 out of the 18 GA's responded). Other award types, like the NIH Exploratory/Developmental Research Grant Award (R21), Research Project Cooperative Agreement (U01), and NIH Small Grant Programme (R03), were much less common. See appendix 2E for a further breakdown of data.

## General Challenges

As with the researcher questionnaire, the GA questionnaire sought to capture the relative importance of various general issues that EU-based GA's may face when their institutions participate in NIH funding programmes. The issues, as shown in Figure 9.1, were communication and information awareness of programmes; lack of administrative support from own organization; cultural differences in management of grants; lack of administrative support from U.S. funding bodies; contractual issues and intellectual property; differences and/or lack of recognition between U.S. and EU policy requirements on issues such as animal safety, protection of human subjects, research integrity, etc.; and lack of complimentary funding. GA's were asked to rate, from 0-5 in increasing degree of challenge, how each issue was a "high" (if rated 5-4), a "medium" (if rated 3), or a "low" (if rated 2-0) challenge as compared with other, non-NIH, programmes. Twelve GA's responded to this group of questions.

Figure 9.1: General Challenges to Participation in NIH Funding Programmes (Shown as High, Medium, or Low)

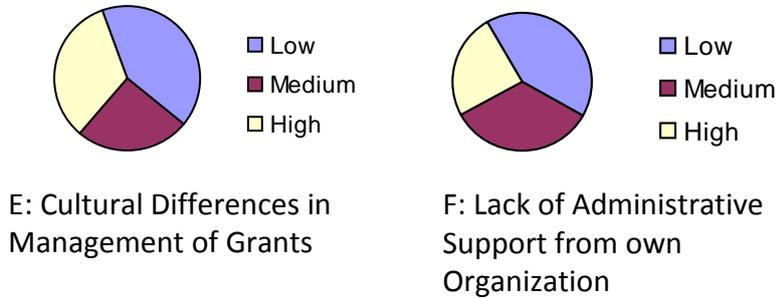
Figure 9.1.1



Of the seven general issues, four were identified as more challenging than the others, with the majority or plurality responding in the "high" category. For GA's, differences between U.S. and EU policy requirements were clearly the most challenging, as show in Figure 9.1.1A, with 67% identifying this issue in the "high" category. The plurality of respondents, as

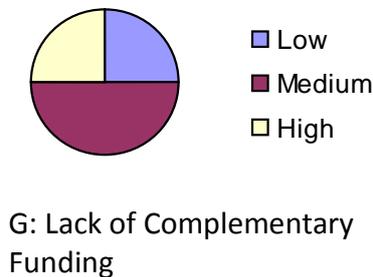
shown in Figures 9.1.1B-D, also scored the lack of administrative support from U.S. funding body, communication and information awareness of programmes, and contractual issues and intellectual property as more challenging than other, non-NIH, programmes.

Figure 9.1.2



Two issues -- cultural differences in the management of grants and lack of administrative support from own organization -- had more mixed reactions, as shown in Figure 9.1.2. Cultural differences in management of grants, shown in Figure 9.1.2C, were not viewed as a significant challenge by half of the GA's but a third scored them as "high" challenges. Forty-two per cent of GA's indicated that lack of administrative support from their own organization was a "low" challenge, a third indicated it was a "medium" challenge, and a quarter as a "high" challenge.

Figure 9.1.3



Lack of complementary funding, shown in Figure 9.1.3G, was a "medium" challenge (i.e., as challenging as other, non-NIH, programmes) according to half the respondents. See appendix 2F for a further breakdown of data.

Figure 9.2: How Grants Administrator’s Institution Approaches Differences between Institutional/National and NIH Policies

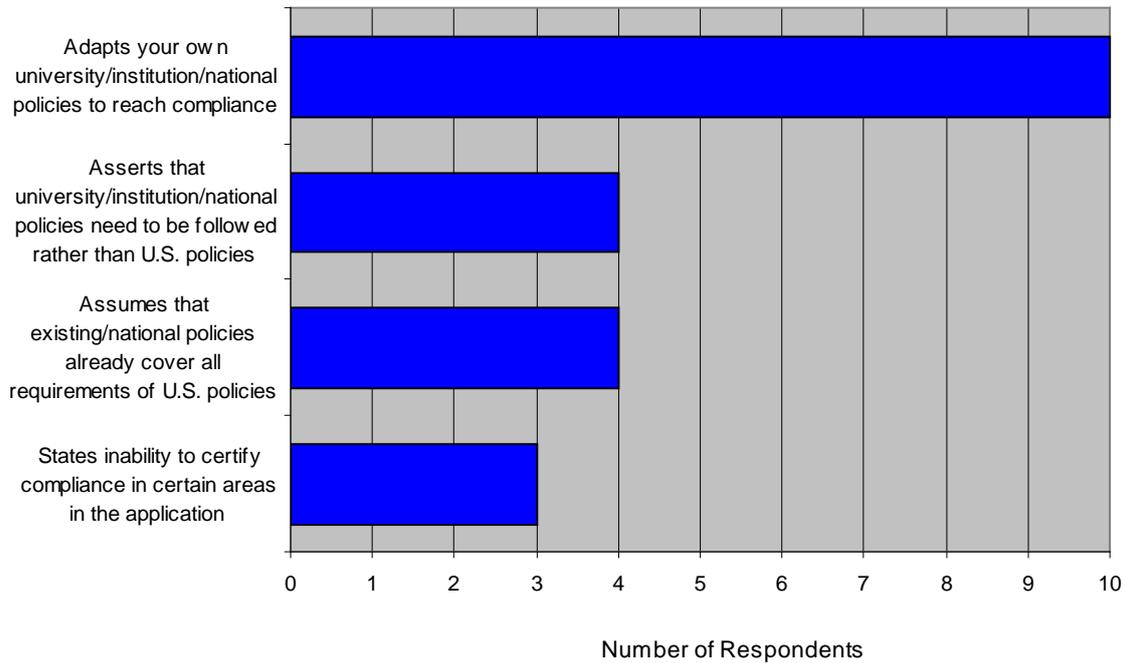


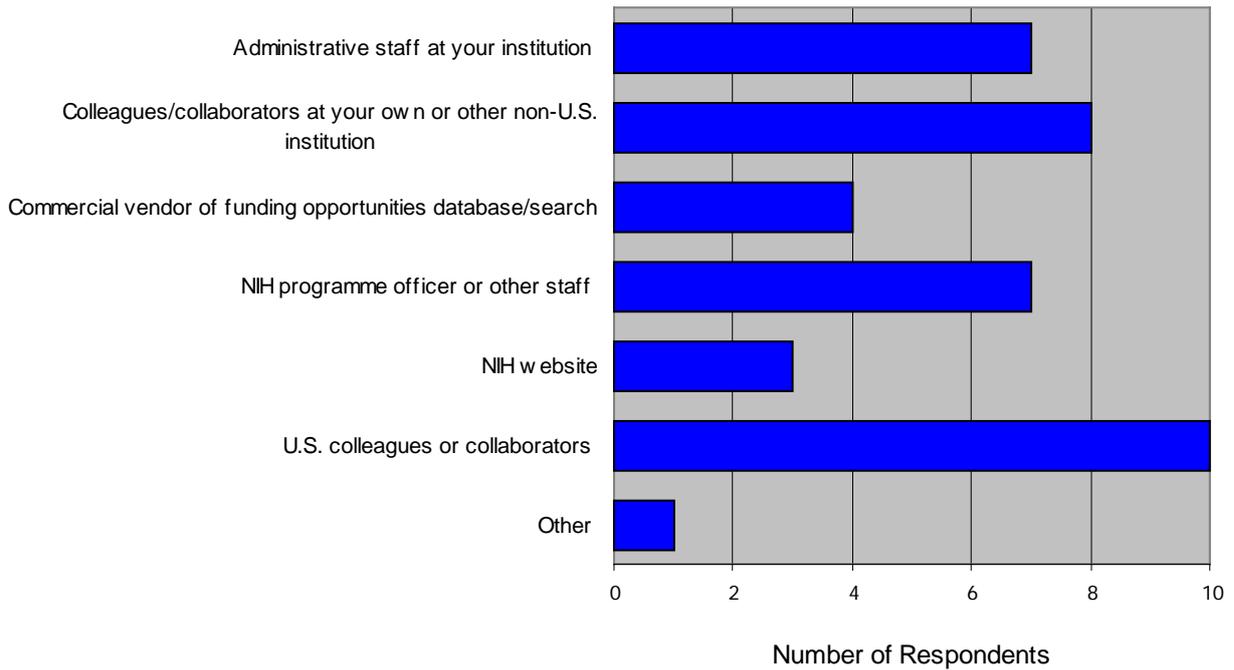
Figure 9.2 shows a breakdown of how GA’s institutions approached to the situation where NIH policies differed from institutional policies. GA’s were asked to choose any of the approaches given that applied to their institution. Out of the 12 GA’s who responded, almost all (10) selected that their institutions adopted their own university/institution/national policies to reach compliance. A minority of the GA’s selected the other approaches. Out of the GA’s responding, none identified “other” or “none of the above.” See appendix 2G for data.

While higher education institutions (13) were reported to take a diverse approach when conflicting policies occurred, the majority of the GA’s from research organizations (5) reported that their organizations adapted their own university/institutional/national policies to reach compliance. See appendix 2H for data.

### Information and Awareness Challenges

In addition to general issues, GA’s were also specifically asked about information and awareness issues about NIH funding programmes. Half of the GA’s responded that new opportunities were easy to hear about. Of those GA’s from higher education institutions, five out of seven stated that it was easy for them to hear about new opportunities. In comparison, of the four out of five GA’s from research organizations responded that it was not easy to hear about new opportunities. Those who found it difficult to find out about new opportunities commonly remarked that NIH materials, including websites, were not clear regarding which programmes were open to European institutions. Please see appendices 2I and 2J for further details.

Figure 9.3: How GA's Hear About New NIH Opportunities



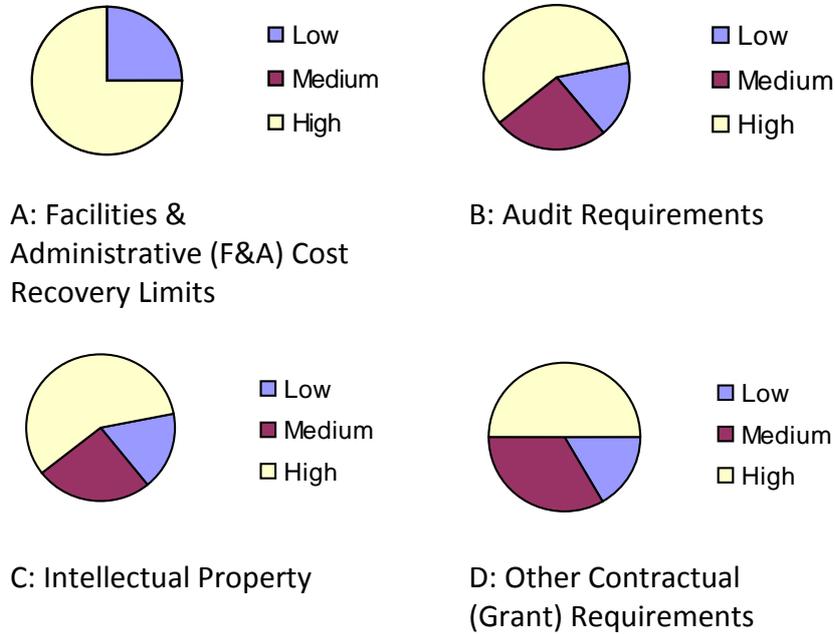
GA's were asked to select from a list of sources from which they hear about new NIH opportunities (more than one option could be selected). The most common source listed, with 10 GA's responding, is their U.S. colleagues or collaborators. Other types of sources involving either staff or colleagues at European institutions or at NIH were nearly as common. The NIH website and commercial vendors were the least common sources for NIH funding opportunities. See appendices 2K and 2L for details.

### Legal, Policy, and Administrative Challenges

Legal, policy, and administrative issues related to EU-based institution participation in NIH funding programmes were probed in further detail. As with the general issues question, GA's were asked to rate from 0-5 by increasing degree of challenge, five issues on how each was a "high" (if rated 5-4), a "medium" (if rated 3), or a "low" (if rated 2-0) challenge as compared with other, non-NIH, programmes. F&A cost recovery limits, audit requirements, budgeting requirements, intellectual property, and other contractual (grant) requirements are the five focal issues described in Figure 9.4.

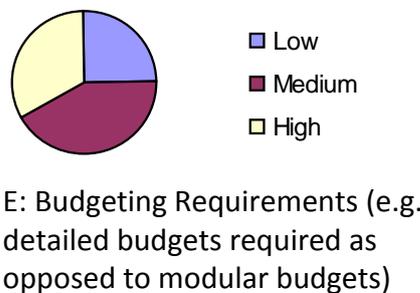
Figure 9.4: Legal, Policy, and Administrative Challenges to Participation in NIH Funding Programmes (12 GA's responded)

Figure 9.4.1



Out of the five issues, four were identified as most challenging, with the majority responding in the “high” category. Figure 9.4.1 shows the four challenges of high importance: F&A cost recovery limits; audit requirements; intellectual property; and other contractual (grant) requirements. Seventy-five per cent of GA responses described F&A, shown in Figure 9.4.1A, as a “high” relative challenge. Both audit requirements and intellectual property issues, shown in Figures 9.4.1B and 9.4.1C, were identified by 58% of the GA’s as “high” challenges. On the issue of other contractual (grant) requirements, 50% of GA described it as a “high” challenge.

Figure 9.4.2



The plurality of GA’s, 42%, indicated that the issue of budgeting requirements was a “medium” challenge (i.e., as challenging as other, non-NIH, programmes), as shown in Figure 9.4.2E. See appendix 2M for data.

With regards to policy issues, GA's were further asked if they had experienced any challenges due to specific criteria in the NIH Grants Policy Statement affecting non-U.S. PI's. According to the Statement, proposals originating from outside the U.S. (but not U.S. domestic applications with foreign components) are subject to these additional review criteria: 1) whether the project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources; and 2) whether the proposed project has specific relevance to the mission and objectives of the NIH Institute/Centre (IC) and has the potential for significantly advancing the health sciences in the United States and the health of the people of the United States. Out of the 12 GA's responding, half responded that they had not experienced any challenges related to these criteria. The other half that did experience challenges had various explanations. These included comments such as "...additional information required is not always described well, so that it's difficult to fulfil the obligations..." and "...it is probably better addressed by the principal investigators themselves..." An additional issue not specified above and raised by one GA was challenges in navigating NIH's internal administration. See appendices 2N and 2O for details.

### **Positive NIH Experiences/Aspects/Issues**

In addition to asking GA's to identify and rate how various issues were challenges, GA's were also asked to comment on positive experiences, aspects, and issues when applying for and/or receiving NIH awards that could be lessons for other, U.S. or European, funding entities. Two GA's responded, focusing on the NIH peer-review system and administration. Responses highlighted the benefits of feedback of the review system along with helpful and knowledgeable programme staff. See appendix 2P for detailed comments.

### **GA Recommendations**

Finally, GA's were asked to make recommendations based on their experiences that could ease or improve research collaboration through NIH funding programmes. Five GA's responded to the open-ended question. Recommendations primarily related to NIH regulations/policies and the application process. In the former category, reimbursement of full F&A costs, clearer presentation of policies (i.e., not in U.S. government legal language), and harmonized compliance requirements between the U.S. and EU were specific recommendations. In the latter category, clearer information about open programmes was recommended. See appendix 2Q for detailed GA recommendations.

## Key Findings

This section summarizes the key findings from the researcher and GA questionnaire results. Responses were dominated by researchers and GA's from the United Kingdom with significant numbers also from Sweden, Germany, France, and Italy, as would be expected from the pattern of NIH funding. Respondents were primarily from higher education institutions who received R01 awards. While the researchers surveyed were those that received direct awards from NIH, the GA's responses indicated that EU-based researchers participate more often in NIH programmes through indirect awards. Despite the expected diversity of responses to the various issues raised in the questionnaires because of variations in national and institutional perspectives of the researchers and GA's surveyed, several issues clearly stood out.

### **Researcher-Friendly Programmes but Policy Differences Make Grant Administration Challenging**

Overall, the researchers indicated positive experiences with NIH programmes. For most of the issues that researchers were asked to rate, either a majority or plurality of researchers indicated they were less challenging than for other, non-NIH programmes. These issues included cultural differences in grant management; broad administrative and contractual issues, including auditing, budgeting, and IP; differences in U.S. and European policies; additional criteria for non-U.S.-based applicants; and lack of complementary funding.

A plurality of researchers indicated only a few issues that were particularly challenging — the general issues of perceived lack of administrative support from their own organizations and, to a lesser extent, communication and information issues and the specific issue of full F&A cost recovery. While a plurality of researchers sought more administrative support from their own organizations, even more researchers responded that lack of administrative support from NIH was not a challenge. Even in the area of communication and information awareness, the majority of researchers indicated that NIH funding opportunities were easy to find (e.g., from colleagues/collaborators and NIH sources). The challenge to address was rather clarity about eligibility and other requirements for EU-based institutions. And as further reflected from GA responses, improved communication and information awareness should balance between too much information, which is often written in U.S. legal or official language, and not enough information about specific, EU-applicable opportunities and requirements.

In contrast to researchers, who generally indicated few challenges, GA's ranked more issues as "high" challenges in both general areas and specific legal, policy, administrative issues. Besides the areas of communication and information awareness and F&A cost recovery, which both pluralities of researchers and GA's indicated as "high" challenges, a plurality or majority of GA's also rated the following as "high" challenges: differences between U.S. and European policies; lack of administrative support from NIH; audit requirements, IP, and other contractual issues. An equal number of GA's responded that did and did not experience challenges related to the specific policy criteria related to non-U.S. applicants.

The increased challenges that GA's describe relative to researchers can reflect a number of factors, not all unexpected. GA's may not necessarily specialize in NIH programmes nor

handle many NIH awards, therefore they may be less familiar and experienced in NIH policies and finding ways to address challenges. Also they likely see more proposals that were unsuccessful in receiving NIH awards. Given the majority of GA's report that their institutions adapt their policies to NIH ones to reach compliance, differences between policies and other administrative requirements could exacerbate these challenges.

### **NIH Funding System is Transparent, Highly Respected, and Source of Support**

Both researchers and GA's highlighted NIH's peer review system as one of the most positive aspects of its programmes and an example for other funding entities. A transparent process for proposal review, including the ability to view reviewers' comments and incorporate them into resubmitted proposals as necessary, was among the most oft cited examples. Moreover, both groups remarked on the relative bureaucratic ease of NIH programmes and they praised NIH programme staff for providing helpful advice and support.

### **Improving Already Open and Efficient Programmes**

To further improve research collaboration through NIH programmes, the top recommendations from researchers and GA's were to improve clarity of eligibility criteria and opportunities for EU-based researchers, increase support for addressing NIH and European differences in administrative requirements and policies, develop specific funding for U.S.-European collaboration, and allow for full F&A cost recovery. These recommendations were not necessarily directed at NIH administration but also toward their own organizations and European policies.

### **Final Caveats**

The main group of researchers that the survey targeted was one that successfully competed for direct awards. These are the researchers who would be expected to have relatively more experience, resources, or support mechanisms for obtaining NIH awards. A majority of these researchers had previously studied or conducted research in the U.S. and had previous U.S. collaborations before they received their first NIH awards. The findings may be positively biased compared with a survey of the entire pool of the EU-based biomedical research community.

## Conclusions

The survey of EU-based researchers and GA's affirmed that NIH programmes on the whole are quite open to European participation, while identifying several challenges to address: awareness of opportunities and clarity of eligibility and requirements at the researcher level; awareness, support, and harmonization of policies at the administration and funding entity level; and the limit on F&A cost recovery.

There are efforts by the EU and the U.S. to support increased awareness of U.S. opportunities and programme participation rules. The EU Delegation in the U.S. has provided information<sup>8</sup> and the Framework Programme has funded recent projects like Link2US to assist EU-based researchers. NIH itself includes dedicated and detailed information on its funding and grants policy for non-U.S.-based researchers.<sup>9</sup> Beyond an increase in outreach to European researchers, there may be room to improve the type of information available, balancing the breadth of information with specific guides targeted to specific national/regional audiences and written in more easily understandable language (i.e., less national or NIH-specific terminology).

Within the United States, different funding entities can and do have differing grant policies and administrative requirements; differences are even starker between countries. As is observed from the European GA's, they are at the front lines of needing to understand and then working to resolve or accommodate these differences. Additional resources to build capacity in working with the funding programmes, such as ones outlined above and workshops that some NIH institutes and centres already offer, would surely be of some benefit. Ultimately, in at least the ease of international participation in any of these and other non-NIH or non-U.S. funding programmes, the reduction of policy and administrative differences and the potential harmonization in some areas should be considered.

Finally, in viewing NIH funding programmes in the light of European participation, comparisons of these national programmes with the inherently multi-national Framework Programme need to be considered cautiously. NIH programmes such as R01 are typically single investigator- or institution-driven that are open with few barriers to EU-based researcher participation, as indicated by the researchers in this survey. As the goal of this survey was to elucidate issues in EU-based researcher participation to better enhance cooperation, the degree to which these programmes successfully support multi-national collaborations (whether or not they were designed to) is less clear. Additional analysis of indirect awards involving EU-based researchers, which implicitly are awards where there is collaboration between U.S. and European researchers, may provide further insights into these programmes as cooperation mechanisms. A complementary question is whether modified or new, and perhaps more specific, instruments are needed to explicitly support bilateral cooperation. While directly supporting bilateral cooperation, such more restrictive instruments, in which formal partnerships may, for example, be required of European and

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<sup>8</sup> see example: *Funding Opportunities for Transatlantic Health Research*, June 2008 ([www.eurunion.org/STETransatlHealthRsrchBroch.pdf](http://www.eurunion.org/STETransatlHealthRsrchBroch.pdf))

<sup>9</sup> see examples: <http://grants.nih.gov/grants/foreign/>  
<http://funding.niaid.nih.gov/researchfunding/int/pages/default.aspx>

U.S. institutions and researchers, should also avoid becoming too bureaucratically burdensome for researchers and GA's.